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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/185,904	11/03/1998	CHRISTEN M. ANDERSON	660088.420	1190

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EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/20/2004

SyK

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/185,904	ANDERSON ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42,44-52,56 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,44-52,56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2003 has been entered.

Status of the Claims

The Amendment and Response filed November 4, 2003 has been entered and considered. Claims 1-41, 43, 53-55, and 58-100 have been cancelled. Therefore, Claims 42, 44-52, and 56-57 are pending and have been considered in this Office Action.

Rejections Withdrawn

The provisional rejection of the claims for double-patenting as being unpatentable over Claims 42, 46, 47, 48, 51, and 57 of copending Application No. 09/393,441 is withdrawn in light of the terminal disclaimer filed.

The rejection of Claims 42, 45, 46, 52, and 56 under 35 U.S.C. 103(a) as being unpatentable over Cozens et al. in view of Le Saux et al. is withdrawn in light of Applicants arguments, the Declaration of Anderson under 37 C.F.R. 1.132, and two

newly cited references; Hatanaka et al. (Biol. Pharm. Bull. (2001) 24(6): 595-599) and Heimpel et al. (J. Biol. Chem. (2001) 276(15): 11499-11506). Hatanaka et al. disclose expression of human ANT1 in yeast. However, Hatanaka et al. teach that the N-terminal region of the human ANT polypeptide had to be replaced with the yeast sequence in order to achieve significant expression. Therefore, Hatanaka et al. provide evidence that one of ordinary skill in the art would not have achieved success by combining the teachings of Cozens et al. and Le Saux or Adrian et al. Heimpel et al. disclose the expression of an ANT from N. crassa in E. coli. Heimpel et al. state that yeast AAC2 and mammalian AAC (also referred to as ANT) are not expressed at significant levels in E. coli and that there is no evidence that the proteins are incorporated into E. coli membranes (p. 11504, Col. 1). Heimpel et al. also discuss the "challenge" of reconstitution of AAC from inclusion bodies and the modification they had to make for successful reconstitution from inclusion bodies (p. 11504, Col. 2). Thus, Heimpel et al. provides additional evidence of failure to express ANT in E. coli. While both Hatanaka et al. and Heimpel et al. are post-filing references, they show that even after the filing date of the present invention, heterologous expression of ANT is not routine.

The rejection of Claims 42, 44-52, 56, and 57 under 35 U.S.C. 103(a) as being obvious over Cozens et al. in view of Adrian et al. and Rosenburg is withdrawn in light of Applicants arguments, the Anderson Declaration, and the newly cited references, Hatanaka et al. and Heimpel et al. for the reasons discussed above.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42, 44, 45, and 46 rejected under 35 U.S.C. 102(b) as being anticipated by Rojo and Walliman (Biochim. Biophys. Acta (1994) 1187: 360-367).

Rojo and Williams provide evidence that the isolation and purification of adenine nucleotide translocators from nature was "simple and rapid" at the time of the invention (see p. 361, Col. 1, line 9). It is noted that while the claims are drawn to a product by process, they have been considered as to whether or not the claimed product is patentably distinguishable over the products of the prior art (see MPEP 2113; product by process claims are not limited by the process steps). The product claimed is considered to be an adenine nucleotide translocator (ANT) polypeptide comprising an amino acid sequence that is at least 95% identical to the sequence set forth in SEQ ID NO:33 and one that is capable of binding an ANT ligand. A search of the sequence database shows that bovine ANT3 is 98% homologous to SEQ ID NO:33. Rojo and Williams teach the isolation and purification of a bovine ANT protein that binds an antibody to ANT (an ANT ligand). Moreover, Rojo and Williams show that the disclosed ANT binds atractyloside, it would be inherent that it would also be capable of binding an

ANT ligand that competitively inhibits binding of atractyloside. The protein of Rojo and Williams is also considered to be indistinguishable from the protein of Claim 46 Rojo and Williams indicate that the ANT polypeptide disclosed therein has been separated from other proteins (see Fig. 2) and since the polypeptide composition of Rojo and Williams would not contain any human ANT polypeptides. ANT3 proteins are expressed in all tissues and have the same molecular weight as the isolated protein shown in Fig. 2 of Williams. Therefore, absent evidence to the contrary, it appears that Rojo and Williams meet the limitations of the present claims.

Claims 42, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Miroux et al. (J. Mol. Biol. (1996) 260: 289-298).

Miroux et al. teach the overexpression of bovine ADP/ATP translocase. ADP/ATP translocase is another name for adenine nucleotide translocator. It is noted that while the claims are drawn to a product by process, they have been considered as to whether or not the claimed product is patentably distinguishable over the products of the prior art (see MPEP 2113; product by process claims are not limited by the process steps). The product claimed is considered to be an adenine nucleotide translocator (ANT) polypeptide comprising an amino acid sequence that is at least 95% identical to the sequence set forth in SEQ ID NO:33 and one that is capable of binding an ANT ligand. A search of the sequence database shows that bovine ANT3 is 98% homologous to SEQ ID NO:33 (see sequence alignment attached to this Office Action). ANT3 is ubiquitously expressed in all cell types. Thus, the bovine ANT disclosed in

Miroux et al. is considered to have a sequence that is at least 95% identical to SEQ ID NO:33. Miroux et al. disclose that the disclosed protein is over-expressed at 18 mg/mL and is isolated in inclusion bodies. The examiner notes that the phrase "is capable of binding" is interpreted to encompass proteins that have the information to bind (and therefore are "capable of" binding) but are not necessarily in the form that binds. Thus, since the protein of Miroux et al. is an ANT protein, it is inherent that it is capable of binding an ANT ligand including an ANT ligand that competitively inhibits the binding of atractyloside or bongkrekic acid (known ANT ligands). Therefore, it appears that the protein disclosed in Miroux et al. is indistinguishable from an ANT protein that is at least 95% identical to SEQ ID NO:33 and is capable of binding an ANT ligand.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42, 44-52, and 56-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to human ANT polypeptides that are at least 95% identical to SEQ ID NO:33. Thus, the claimed genus encompasses ANT polypeptides that are at

least 95% identical to SEQ ID NO:33 and are human. The Specification only provides one species; SEQ ID NO:33. A search of the sequence databases shows that there are non-human ANT sequences that are greater than 95% identical to SEQ ID NO:33 (see sequence alignment attached to this Office Action). Bovine ANT is 98% identical to SEQ ID NO:33. How many and which amino acids would have to be changed for this sequence to be considered "human"? At a time when recombinant expression and mutagenesis are routine, some type of characteristic feature of human ANT sequences would be required for one of skill in the art to be able to distinguish a human sequence from non-human. For example, if an ANT protein was heterologously expressed, what sequences of all the sequences that are at least 95% identical to SEQ ID NO:33 would be considered "human". Therefore, given that there are non-human sequences that are greater than 95% identical to SEQ ID NO:33, that the Specification provides only one species of the genus, and that all of the human ANT sequences are not presently known, the present Specification has not provided sufficient written description as to what sequences are considered human.

Conclusions

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-

0958. The examiner can normally be reached on Tuesday, Thursday, and Friday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HS

Holly Schnizer
February 6, 2004

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